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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,477	08/22/2006	Torsten Brandenburger	05116835	1954
26565 7590 12/24/2008 MAYER BROWN LLP P.O. BOX 2828 CHICAGO, IL 60690				
EXAMINER				
MARCECICH, ADAM M				
ART UNIT		PAPER NUMBER		
3761				
NOTIFICATION DATE		DELIVERY MODE		
12/24/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

# Office Action Summary

**Application No.**

10/550,477

**Applicant(s)**

BRANDERBURGER ET AL.

**Examiner**

Adam Marcetich

**Art Unit**

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-10 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 23 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/5508)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. Germany 103 13 760.2, filed on 27 March 2003 has been received.

### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 October 2008 has been entered.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application

filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 5, 6, 9 and 10 are rejected under 35 U.S.C. 102(a or e) as being anticipated by Knierbein (US Patent 6,364,143).

5. Regarding claim 1, Knierbein discloses a connector for packings containing medical liquids, particularly infusion, transfusion or enteral bags, comprising:

a connecting part with a passage for accommodating a spike for withdrawal of the liquid (column 3, lines 32-54 and Fig. 1, base body 2 having passage);

a closure part which can be fitted onto the connecting part and closes the passage in the connecting part (column 3, lines 32-54 and Figs. 1-2, protective cap 5 closing passage in base body 2);

characterized in that the connecting part has an elastically deformable pinching-off part which re-assumes its original shape again after pinching and is designed as a tubular portion (column 3, lines 32-54 and Fig. 1, tubular upper part 4);

with a noncircular cross section (column 3, lines 32-54 and Fig. 1, base body 2 comprising radially projecting wing-like pieces 7 and 8 with non-circular cross section);  
and

in that the pinching-off part merges into a base part which widens to both sides and which can be integrated in the packing (column 3, lines 32-54 and Fig. 1, boat-shaped lower part 3).

Regarding the amended limitation of an elastically deformable pinching-off part re-assuming its original shape again after pinching, it is the Examiner's position that

tubular upper part 4 of Knierbein is capable of re-assuming its original shape again after pinching. When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions presumed to be inherent (MPEP 2112-2112.01). A prima facie case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim (in this case, an elastically deformable pinching-off part) except for a property or function (in the present case, re-assuming its original shape again after pinching) and the examiner can not determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to applicant, as per *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

To clarify, Examiner notes that the terms "pinching," "elastic" or "elastically deformable" are not given special meaning in the immediate specification. Therefore, Examiner interprets the limitation of "re-assuming an original shape again after pinching" broadly to include an elastically deformable pinching-off part made of materials that are recognized as elastic. Knierbein discloses tubular upper part 4 as injection molded (col. 3, lines 32-40), which includes materials like polypropylene (cols. 3-4, lines 61-6). Polypropylene is generally recognized as an elastic material, and therefore capable of re-assuming its original shape again after pinching.

6. Regarding claim 5, Knierbein discloses a connector characterized in that the closure part has a cap-shaped bottom part (col. 3, lines 41-49 and Fig. 1, flange 10. Examiner interprets the language "cap-shaped" broadly to include a hollow, cylindrical

shape. Examiner notes that a more specific definition of "cap-shaped" does not appear in the immediate specification.);

7. which is adjoined, via an annular break zone (col. 3, lines 46-54 and Fig. 1, annular fracture zone 12);

8. by a top part that can be broken off (col. 3, lines 46-54 and Fig. 1, wings 13 and 14). Examiner interprets the limitation of "that can be broken off" broadly to include wings 13, 14 being removed with protective cap 5.

9. Regarding claim 6, Knierbein discloses a connector characterized in that the top part that can be broken off is designed as a flat grip piece (Fig. 1, wings 13 and 14 forming a flat grip piece).

10. Regarding claim 9, Knierbein discloses a connector characterized in that the base part is designed in the shape of a boat (col. 3, lines 32-40 and Fig. 1, boat-shaped lower part 3 having boat-shape).

11. Regarding claim 10, Knierbein discloses a packing for medical liquids, particularly an infusion, transfusion or enteral bag, having at least one connector as claimed in claim 1 (col. 3, lines 32-40, conventional collapsible bag for medicinal liquids).

#### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Knierbein (US Patent 6,364,143) in view of Burns (US Patent 5,494,170).

15. Regarding claim 2, Knierbein discloses the invention as substantially claimed, see above. However, Knierbein lacks a snap fit as claimed [claim 2]. Burns discloses a closure part and connecting part secured with a snap fit (column 2, lines 61-67 and column 3, lines 13-23, Fig. 1, cam ring 4 and cooperating cam follower ring 16 forming snap-fit). Burns provides the advantage of temporary closure between a cover and medicament dispenser. This allows a user to reseal the container after withdrawing fluid with a piercing member. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Knierbein as discussed with the snap fit as taught by Burns in order to temporarily close a medicament dispenser.

16. Regarding claim 3, Knierbein discloses the invention as substantially claimed, see above. However, Knierbein lacks a self-sealing membrane arranged between a

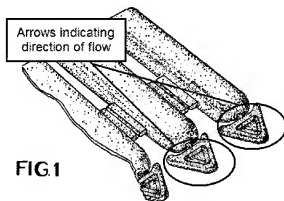
connecting part and closure part as claimed [claim 3]. Burns discloses a self-sealing membrane (column 2, lines 8-11, 53-58, Fig. 1 stopper 12). Burns provides the advantage of a repeatedly pierceable membrane that allows for multiple withdrawals of fluid or medicament with a piercing member. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Knierbein as discussed with the self-sealing membrane as taught by Burns in order to provide multiple sample withdrawals from a container.

17. Regarding claim 4, Knierbein discloses the invention as substantially claimed, see above. However, Knierbein lacks a self-sealing membrane held clamped with elastic deformation between a connecting part and a closure part as claimed [claim 4]. Burns discloses a self-sealing membrane held clamped with elastic deformation between a connecting part and a closure part (column 2, lines 53-58 and Fig. 1, stopper 12 depicted as held between tube 1 and shield 11). Burns provides the advantage of simple construction in addition to multiple withdrawals as discussed for claim 3 above. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Knierbein as discussed with the clamped, self-sealing membrane as taught by Burns in order to provide simple construction and multiple sample withdrawals.

18. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knierbein (US Patent 6,364,143) in view of LeMarr et al. (US D456,507).



19. Regarding claims 7 and 8, Knierbein discloses the invention as substantially claimed, see above. However, Knierbein lacks an arrow designed as a recess and/or as a raised structure as claimed [claims 7 and 8]. LeMarr discloses a nebulizer vial comprising an arrow designed as a recess and/or as a raised structure (see annotated Fig. 1 below). LeMarr provides the advantage of showing a user where fluid will exit a container when opened. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Knierbein as discussed with the arrow as taught by LeMarr in order to instruct a user.



Annotated Fig. 1 of LeMarr et al. (US D456,507)

### ***Response to Arguments***

20. Applicant's arguments filed 08 October 2008 have been fully considered but they are not persuasive.

21. Applicant asserts that the term "elastically deformable" has been given a special meaning, citing page 3, lines 4-9 and to page 6, lines 10-14 of the Specification "In addition, the pinching-off part makes it possible to close the connector with a clip or the like during use in a hospital." However, Examiner interprets this disclosure as an example, and not a special definition. Polypropylene is known as a flexible, elastomeric material especially useful in forming living hinges (online encyclopedia article, Polypropylene, p. 4, ¶ 5). Additionally, polypropylene exists in different grades (online article, "Elastic Plastic Moving From Lab To Industry" p. 1, ¶ 3, and p. 2, ¶ 2). Lastly, the thickness of tubular upper part 4 also influences its ability to be deformed.

22. Applicant contends that the claim language contained in Knierbein suggests that the connecting part may only be deformed with heat. Examiner notes that the written description of Knierbein is relied upon for teaching an elastically deformable material.

23. Applicant reasons that when used in the dimensions disclosed in Knierbein, both polyolefins and polypropylene are thermoplastic plastic materials that are only deformable upon heating, and therefore the connecting part disclosed in Knierbein cannot be deformed simply by applying pressure. Examiner notes that Knierbein is silent regarding dimensions of tubular upper part 4.

24. Applicant asserts that none of the other illustrations of Knierbein illustrate a non-circular cross section. In contrast, as illustrated in Figure 5 of the pending application, it clear that the Applicant teaches a connecting part that has a non-circular cross section. Examiner notes that radially projecting wing-like pieces 7 and 8 are relied upon as teaching a non-circular cross section.

25. Applicant contends that the method of connection disclosed in Knierbein limits it to having a circular cross section that is not elastically deformable, since in order for an external threading be able to be screwed into the coupler nut and form a seal the upper tubular part cannot be elastically deformable, and that in order for the upper tubular part to deform with slight pressure, it would be incapable of forming the seal as disclosed.

Examiner notes that the claims are drawn to a device, not a method of connection.

Additionally, during connection with a nut, an external thread may be interpreted as "pinched" by the connecting nut since compression or frictional deformation occurs.

26. Applicant reasons that if the connection part is non-circular in cross section, the connection of the external threading and a coupler nut would not result in the claimed seal of Knierbein. Examiner notes that radially projecting wing-like pieces 7 and 8 are relied upon as teaching a non-circular cross section.

27. Applicant asserts that one of ordinary skill in the art, when reading Knierbein in view of LeMarr or Bums would not be taught or suggested to develop a connecting part that was non-circular, elastically deformable with minimal pressure and re-assumed its original shape after pinching. Examiner notes that Knierbein is relied upon as teaching the claimed non-circular, elastically deformable pinching-off part as discussed above.

28. If any amendments to the claims are desired for overcoming rejections of record, Examiner recommends phrasing them in positive language. While negative limitations are legitimate and do not preclude patentability, positive recitations are generally more effective. There is nothing inherently ambiguous or uncertain about a negative limitation, as long as it is properly supported by the specification. See MPEP 2173.05(i), Negative

Limitations. However, adding language to positively claim structures and functions is generally more helpful in clearly defining the invention as compared to negative limitations, since the presence of a structure or function is more easily seen, depicted or discerned than its absence or omission.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/  
Examiner, Art Unit 3761

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Primary Examiner, Art Unit 3761  
19 December 2008